REMARKS

Claims 39-53 remain in this application. The original application, from which the instant application is a continuation, contained Claims 1-43, which claims were canceled by preliminary amendment and Claims 44-58 added. The Examiner renumbers Claims 44-58 to be Claims 39-53. As such, Applicants continue the nomenclature suggested by the Examiner herein.

Claims 39-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,096,339. Applicants are willing to submit a terminal disclaimer over U.S. Patent No. 6,096,339 if the instant application is allowed.

Claims 39-53 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Jao et al.* (U.S. Pat. No. 5,151,338). The Examiner asserts that *Jao* teaches a similar dosage form wherein the distinctions from the instant application, namely, the feature of a percentage deviation of not more than 5% from a mean rate of release by the use of controlled particle sizes for the drug and/or hydrophilic polymer, are not critical, thus making the invention obvious. Applicants respectfully traverse this rejection as discussed below.

Rejections Under 35 U.S.C.§ 103(a)

Claims 39-53 are rejected under 35 U.S.C. §103(a), as being unpatentable over *Jao, et al.* (US. Pat. No. 5,151,338). In particular, the

Examiner asserts that *Jao* discloses the instant invention and that the improvements of the instant invention are obvious and not critical.

Applicants respectfully traverse this rejection because Applicant's invention is not *prima facie* obvious from the disclosure of the cited reference. In order to be *prima facie* obvious over a reference or a combination of references, the reference must describe or teach each of the claim limitations and the references must themselves suggest their particular combination and a reason for that combination without reference to Applicant's application. The references, either taken alone or in combination, are not considered to establish the *prima facie* obviousness of those claims, and the Examiner has not met the burden in properly rejecting the claims.

This rejection is respectfully traversed because *Jao* does not motivate towards Applicants' claim element for a uniform rate of release of less than 5% deviation; much less motivate toward Applicants' claim element for use of controlled particle sizes to obtain a more uniform rate of release. Furthermore, the Examiner provides no teaching from *Jao* or any other art to suggest that controlled particle size could create a more uniform rate of release; much less that *Jao* suggests modification of its system to any other rate of release by controlling particle sizes. Indeed, *Jao* is silent as to the effect of particle size within the dosage form and is silent on the need for a substantially uniform rate of release providing less than 5% deviation. Throughout *Jao* only the amount of drug and the amount and molecular weight of the polymer are described. There

is no motivation in *Jao* to modify the delivery rate, much less to look to the particle sizes to modify the delivery rate or its uniformity.

Moreover, a recurring issue in controlled release drug delivery is to provide uniformity in the release of the drug from the dosage form. With control can come the need for release at a uniform rate so as to provide a constant delivery of drug to the subject for efficacious therapy. As such, the present invention claims a dosage form for delivery of a drug at a rate having a percentage deviation of not more than 5% from a mean release rate over a prolonged period of time. Substantially uniform is defined as a 100% drug delivery rate at +/-5% variation from the norm. Applicants' Application at page 27. The expression "uniform" as defined for the purpose of this invention means a deviation of +/-5% from a constant, 100%, nonvarying delivery. Applicants Application at page 28. As such, the deviation of +/-5% is a critical component of the invention, which is expressly incorporated into the claim limitation and supported in the application.

Therefore, it would not have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to prepare a controlled release dosage form utilizing controlled drug and polymer granule sizes to provide for a substantially uniform rate of release having a less than 5% deviation from the constant.

For these reasons, Applicants assert that the rejection of claims 39-53 is not appropriate and withdrawal of the rejection is respectfully solicited.

Applicants respectfully submit that Claims 39-53 are novel and nonobvious over the art cited and are in a position for allowance.

Reconsideration of the application is respectfully requested. Please direct any questions to the undersigned attorney at (650) 564-5171.

Respectfully submitted,

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